**IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK**

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| AARON HAIMOWITZ and CARYN LERMAN,<br><br>Plaintiffs,<br>v.<br><br>NOVARTIS PHARMACEUTICALS CORPORATION,<br>Defendant. | **Civil Action No. 1:09-cv-10068-JFK**<br><br>**ORAL ARGUMENT SET FOR OCTOBER 8, 2015 AT 2:15 P.M.** |

# NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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## INTRODUCTION

The Court should dismiss all claims of plaintiffs Aaron Haimowitz and Caryn Lerman,[1] alleging that their late mother, Beryl Haimowitz, contracted osteonecrosis of the jaw ("ONJ") from Novartis Pharmaceutical Corporation's ("Novartis") prescription bisphosphonate medication, Aredia®.[2] Plaintiffs' tort claims are barred by New York's three-year statute of limitations because Ms. Haimowitz knew by 2002 at the latest that she had ONJ that could be related to her Aredia® therapy, but did not file suit until December 2009, more than seven years later. New York's four-year statute of limitations similarly bars her warranty claims because she last received Aredia® in 2002, but failed to file suit for over seven years.

First, under New York law governing tort claims, "[t]he three year limitations period runs from the date when plaintiff first noticed symptoms, rather than when a physician first diagnosed those symptoms, so the significant date is when plaintiff began experiencing symptoms, not when [the physician] diagnosed them." *Galletta v. Stryker Corp.*, 283 F. Supp. 2d 914, 917 (S.D.N.Y. 2003). Ms. Haimowitz knew she had an injury to her jaw by 1997, more than twelve years before she brought this lawsuit. Even assuming N.Y. C.P.L.R. §214-c(4)'s "unknown cause" extension of the statute of limitations applied, Ms. Haimowitz's claims are still untimely because she failed to file her lawsuit within one year of discovering the cause of her injury. Ms. Haimowitz's medical records show that she learned, and informed her doctors that Aredia®

[1] The Court substituted Aaron Haimowitz and Caryn Lerman as the plaintiffs in this litigation upon the death of Beryl Haimowitz. *See* Order, January 15, 2014, ECF No. 8-7 (granting motion to substitute party).

[2] Although Ms. Haimowitz received at least one dose of Zometa®, another intravenous bisphosphonate medication sold by Novartis, her complaint only alleges injury related to her Aredia® use. *See* Complaint ¶¶ 1, 13-15, ECF No. 1

might have caused her ongoing ONJ and immediately stopped taking a similar bisphosphonate medication in 2002 – over 7 years before she filed her complaint.

Second, under New York law, Ms. Haimowitz's breach of warranty claims accrued for purposes of the applicable four-year statute of limitation when she last received Aredia®. N.Y. U.C.C. §2-275. Because Ms. Haimowitz last received Aredia® in 2002, but did not file suit until 2009, the Court also should dismiss her warranty claims.

Finally, even if Maryland's statutes of limitations applied, Ms. Haimowitz's claims would be untimely. Under Maryland law, Ms. Haimowitz had three years to file her tort claims after discovering Aredia® might have caused her ONJ in 2002, but missed the deadline by over four years. Md. Code Ann., Cts. & Jud. Proc. §§ 5-101, 5-115; *Bragunier Masonry Contractors, Inc. v. Catholic Univ. of Am.*, 796 A.2d 744, 757 (Md. 2002). Further, because Maryland's four-year limitations period for warranty claims is identical to New York, her warranty claims would still be untimely under Maryland law. Md. Code Ann., Com. Law § 2-725.

## STATEMENT OF FACTS

Ms. Haimowitz, a citizen and resident of Maryland, filed this lawsuit in the United States District Court for the Southern District of New York on December 8, 2009. Complaint ¶¶ 2, 5, ECF No. 1. The Complaint alleges that Aredia® caused Ms. Haimowitz to develop ONJ, and seeks recovery under theories of strict liability, negligence, and breach of express and implied warranties. *Id*. at ¶¶ 1, 14, 15-43.

The Judicial Panel on Multidistrict Litigation transferred the case to the Middle District of Tennessee pursuant to 28 U.S.C. § 1407 for coordinated and consolidated proceedings. 3/29/2010 Transfer Order, ECF No. 6. On September 26, 2014, the MDL Court remanded this

case back to the Southern District of New York before any discovery beyond medical record collection took place.[3] 9/26/2014 Remand Order, ECF No. 7.

## I. MS. HAIMOWITZ NEEDED AREDIA® THERAPY TO PREVENT BONE DAMAGE FROM HER CANCER.

Ms. Haimowitz was diagnosed with multiple myeloma in December 1995. Novartis's 56.1 Statement of Undisputed Facts in Supp. of Mot. for Summ. J. ("SUF") (filed contemporaneously) ¶¶ 1-2. Each year, approximately 27,000 new diagnoses and over 11,000 deaths occur in the United States from multiple myeloma, an invasive blood cancer of the bone marrow that suppresses the body's immune system. *See* AM. CANCER SOCIETY, MULTIPLE MYELOMA at 2-3, 8, 10 (2015) (Exhibit 1 to Aff. of Donald R. McMinn in Supp. of Novartis's Mot. for Summ. J. ("McMinn Aff. Ex.") (filed contemporaneously)); MULTIPLE MYELOMA FOUNDATION, MULTIPLE MYELOMA DISEASE OVERVIEW, 2, 5 (2012) (McMinn Aff. Ex. 2). Complications from multiple myeloma include intractable bone pain and pathologic fractures (bone breaks caused by cancer eating away at bone), and can progress to other devastating conditions, such as spinal cord compression (which can result in paralysis), and hypercalcemia of malignancy (potentially fatal elevated blood calcium). *See* AM. CANCER SOCIETY, MULTIPLE MYELOMA at 3, 8-9; MULTIPLE MYELOMA FOUNDATION, MULTIPLE MYELOMA DISEASE OVERVIEW at 3, 5; JR Berenson et al., *Zoledronic Acid Reduces Skeletal-Related Events in Patients with Osteolytic Metastases: A Double-Blind, Randomized Dose-Response Study*, 91(7) CANCER 1191-1200 (2001) (McMinn Aff. Ex. 3). Untreated, the average survival of patients with multiple myeloma is approximately 6 months. ML Smith et al., *Malignancy: Myeloma – the Elusive Cure*, 5 HEMATOLOGY 27, 27 (2000) (McMinn Aff. Ex. 4).

[3] No case-specific depositions have been taken in this case to date. Because Ms. Haimowitz's medical records indisputably show that her claims are time-barred, it is not necessary to conduct depositions before deciding this motion.

To protect her bones from further damage from multiple myeloma, Ms. Haimowitz's oncologist, Dr. Ivan K. Rothman, prescribed her Aredia®. Plaintiff Fact Sheet at 21-22 (McMinn Aff. Ex. 5). Aredia® is a Food and Drug Administration ("FDA")-approved intravenous bisphosphonate medication prescribed for the prevention of bone damage in patients with multiple myeloma or cancer that has attacked their bones. 10/31/1991 Letter from Bilstad to Hanagan (ZA-0004087 to -0004088) (McMinn Aff. Ex. 6); 9/1995 Aredia® Label at 1-2 (McMinn Aff. Ex. 7); 9/22/1998 FDA Approval Letter (ZA-0693579 to -0693580) (McMinn Aff. Ex. 8). By effectively preventing the debilitating bony complications of multiple myeloma, Aredia® became a standard of care medication for patients with multiple myeloma and revolutionized the treatment of cancer patients. LS Rosen et al., *Zoledronic acid versus pamidronate in the treatment of skeletal metastases in patients with breast cancer or osteolytic lesions of multiple myeloma: a phase III, double-blind, comparative trial*, 7(5) CANCER 377-387 (2001) ("Intravenous pamidronate (90 mg) is the current standard of care for the treatment of patients with . . . osteolytic lesions associated with multiple myeloma. Pamidronate . . . has been shown to significantly prolong the time to first skeletal-related event (SRE) and to significantly reduce the incidence of SREs for up to 21 months in patients with multiple myeloma…") (McMinn Aff. Ex. 9); B Petrut et al., *A primer of bone metastases management in breast cancer patients*, 15 CURRENT ONCOL. 550-57 (2008) ("The aims of bisphosphonates are to prevent and delay [skeletal related events], to reduce bone pain, and to improve quality of life. Bisphosphonate therapy appears to have revolutionized treatment of bone metastases….") (McMinn Aff. Ex. 10).

Ms. Haimowitz received Aredia® on a monthly basis from December 29, 1995 through

May 28, 1997; and from August 8, 1997 through March 29, 2002.[4] SUF ¶¶ 3-4.[5] At the time she was diagnosed with multiple myeloma and treated with Aredia®, Ms. Haimowitz lived in New York. SUF ¶¶ 2, 35-38.

## II. MS. HAIMOWITZ HAD ONJ SYMPTOMS IN 1997 AND KNEW THAT AREDIA® COULD HAVE CAUSED HER ONJ BY 2002.

Bisphosphonate-related ONJ is defined as exposed bone in the jaw of more than eight-weeks duration in a patient who has undergone Aredia® (or Zometa®) treatment and not received radiation to the jaw. SUF ¶¶ 5-6. Oral surgeons also have referred to this condition as bisphosphonate-associated osteomyelitis or avascular necrosis of the jaw. SUF ¶¶ 7-8. Ms. Haimowitz's medical records show that she experienced symptoms and jaw problems consistent with ONJ as early as November 1997, SUF ¶¶ 9-11, 14, more than twelve years before she brought this lawsuit in December 2009. At that time, Ms. Haimowitz lived in New York. SUF ¶ 37.

On July 30, 1997, while off Aredia®, Ms. Haimowitz underwent extraction of a non-restorable, lower left molar (tooth #18) by Dr. Eugene Herman. SUF ¶ 14. Healing was normal until November 18, 1997, when Ms. Haimowitz complained of swelling and pain and exposed

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[4] In 2001, Aredia® went off patent and generic pamidronate manufactured by other companies became available. *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 4387376, at *1 (M.D. Tenn. Nov. 30, 2007) (McMinn Aff. Ex. 11). Aredia®'s generic equivalent, pamidronate, remains on the market as an FDA-approved drug. 5/6/2002 FDA Approval Letter to Gensia Sicor Pharms., Inc. (McMinn Aff. Ex. 12); FDA Orange Book Information Files, Appendix A, at A-41 (listing approved drugs) (McMinn Aff. Ex. 13). It is unclear whether Ms. Haimowitz received only brand Aredia® (rather than a generic drug) during the course of her treatment but that issue is not material for purposes of this dispositive Motion. If the case is not dismissed, Novartis reserves the right to challenge plaintiffs' claims on product identification grounds.

[5] Ms. Haimowitz also received a dose of Zometa® on May 2, 2002. 5/2/2002 Health Care Record (2295-0006) (McMinn Aff. Ex. 14). Like Aredia®, Zometa® is an FDA-approved, intravenous, bisphosphonate medication prescribed for the prevention of bone damage in patients with multiple myeloma or cancer that has attacked their bones. 2/22/2002 FDA Approval Letter (McMinn Aff. Ex. 15). Zometa® remains on the market as an FDA-approved drug. *See* FDA Orange Book Information Files, Appendix A, at A-59 (listing approved drugs) (McMinn Aff. Ex. 13).

bone at the extraction site, symptoms consistent with what was subsequently diagnosed as ONJ caused by her treatment with Aredia.® SUF ¶¶ 9-11, 14. Thereafter, she continued to experience infection and exposed bone in her jaw between November 1997 and August 2002, and received treatment from New York oral surgeons, including Dr. Salvatore Ruggiero, one of the first – if not the first – oral surgeons in the United States to identify a possible causal connection between Aredia® and jaw problems like ONJ and osteomyelitis. SUF ¶¶ 13-22. In June 2002, after receiving bisphosphonates for seven years and being treated for jaw problems for five years, Ms. Haimowitz moved to Maryland. SUF ¶¶ 37-38.

It cannot reasonably be disputed that by September 2002, at the latest, more than seven years *before* bringing this lawsuit, Ms. Haimowitz believed that Aredia® was responsible for her jaw condition. This belief was evident on September 13, 2002, when she informed her current oncologist, Dr. Flavio Kruter, that her prior oral surgeon in New York and her current oral surgeon in Maryland, Dr. Robert Ord, had told her that her treatment with Aredia® was responsible for her jaw problems. SUF ¶ 23. As noted by Dr. Kruter in his records:

> The patient brings up an intriguing point of having been told by her previous and present oral surgeon that THEY HAVE NOTICED A CLUSTER OF PATIENTS WITH OSTEOMYELITIS THAT HAVE BEEN TREATED WITH PAMIDRONATE ON A LONG-TERM BASIS.
> …
> The patient raises an interesting concern regarding the HIGHER INCIDENCE OF OSTEOMYELITIS IN PATIENTS UNDERGOING THERAPY WITH PAMIDRONATE. I will be doing some investigation on that including discussing with her oral surgeon in New York who related that information to her.

*Id.* (emphasis added). Based on this information, Dr. Kruter stopped Ms. Haimowitz's treatment with Zometa® that day. *Id.* As noted by Dr. Kruter, on November 22, 2002:

> She had been on Aredia and presently was on Zometa until July 2002. That was discontinued given personal communication information obtained from her previous oral surgeon in New York and also from Dr. Ord at University, where they have noticed a

> CLUSTER OF PATIENTS WHO HAVE DEVELOPED OSTEOMYELITIS THAT HAD BEEN ON BISPHOSPHONATE.

SUF ¶ 24 (emphasis added).

Ms. Haimowitz's doctors continued to recognize the connection between her jaw problems and her bisphosphonate therapy in her 2003 medical records, made more than six years before she filed suit, which clearly reflect her doctors' views that she had jaw problems induced by Aredia®. SUF ¶ 25. Her Maryland oral surgeon, Dr. Robert Ord, for example, repeatedly refers in his records from 2003 forward to Ms. Haimowitz's "Aredia-induced Osteonecrosis" or "bisphosphonate" jaw problems. SUF ¶¶ 26-30. Consistent with treatment protocol for bisphosphonate-related ONJ at that time, Dr. Ord also recognized the need to treat Ms. Haimowitz's ONJ conservatively, avoiding dental surgery where possible. SUF ¶¶ 31-33. Although Dr. Ord has not been deposed in this case, he testified in a different lawsuit that he first learned of the connection between bisphosphonates in 2002-2003, when treating a patient who had moved from New York to Maryland who, apparently, is Ms. Haimowitz:

> Q. Do you recall when you learned that bisphosphonates could cause osteonecrosis of the jaw?
>
> A. It must have been 2002, 2003.
>
> Q. And do you remember how you learned that?
>
> A. Yes.
>
> Q. And how is that that you learned?
>
> A. I had a lady who had a nonhealing jaw bone lesion that I ended up resecting the jaw bone. At the time, I thought she had a sclerosing osteomyelitis. She had previously been treated, I believe, for myeloma in New York. One of my colleagues, Doctor Saul Ruggiero, who at that time was an attending in Long Island Jewish, phoned me up and said, this patient -- because I sent him -- as a courtesy, I sent him a letter to say that I had seen his patient. She had moved to Baltimore and I treated her.

> And [he] told me that he had seen a number of patients with what he believed was a new condition caused by bisphosphonates. And he thought this lady was one and had I seen any, and I said I did not think I had. And he asked me to check through my records, which I did, and I found a number of patients with the condition that were previously not noticed.

SUF ¶ 34.

## ARGUMENT

### I. SUMMARY JUDGMENT STANDARD

District courts are required to grant summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Although the plaintiffs are entitled to have the facts construed in their favor, they cannot rest on their pleadings' allegations, *see* Rule 56(e), and "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). When deciding such motions, courts cannot consider inadmissible evidence. Furthermore, courts must "view the evidence presented through the prism of the substantive evidentiary burden[,]" so there must be sufficient evidence on which a jury could reasonably find for the plaintiffs. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules [of Civil Procedure] . . . ." *Celotex Corp. v. Catrett ex rel. Catrett*, 477 U.S. 317, 327 (1986). "The mere existence of a scintilla of evidence in support of the plaintiff[s'] position will be insufficient" to defeat a defendant's summary judgment motion. *Anderson*, 477 U.S. at 252 (quotation marks and citation omitted). The plaintiffs "may not rely simply on conclusory allegations or speculation . . . but instead must offer evidence to show that [their] version of the events is not wholly fanciful." *Jorgensen v. Epic/Sony Records*, 351 F.3d 46, 51 (2d Cir. 2003) (quoting *Morris v. Lindau***,** 196 F.3d 102, 109 (2d Cir.1999)) (internal quotes omitted).

## II. NEW YORK LAW APPLIES TO PLAINTIFFS' CLAIMS IN THIS CASE.

Ms. Haimowitz filed her lawsuit in the Southern District of New York on December 8, 2009. New York law therefore governs procedural matters in this case, including the statute of limitations. *See Intellivision v. Microsoft Corp.*, 784 F. Supp. 2d 356, 368 n.9 (S.D.N.Y. 2011) ("Although Connecticut law governs the plaintiffs' substantive claims to the extent it conflicts with New York law, New York law governs procedural issues such as the statute of limitations."). "Under New York's 'borrowing statute,' N.Y. C.P.L.R. § 202, a case filed by a non-resident plaintiff requires application of the shorter statute of limitations period . . . provided by either New York or the state where the cause of action accrued." *Cantor Fitzgerald Inc., v. Lutnick*, 313 F.3d 704, 710 (2nd Cir. 2002).

While Ms. Haimowitz moved to Maryland in June 2002, SUF ¶¶ 37-38, her claims accrued in New York. Under New York's choice-of-law rules, New York law governs plaintiffs' claims because Ms. Haimowitz's alleged injury occurred in New York, she resided in New York at the time she developed ONJ, and all of her Aredia® infusions occurred in New York.[6] SUF ¶¶ 2, 14-22, 35-37, 39-41; *see also Schultz v. Boy Scouts of Am., Inc.*, 480 N.E.2d 679, 683-84 (N.Y. 1985) ("[W]hen the defendant's negligent conduct occurs in one jurisdiction and the plaintiff's injuries are suffered in another, the place of the wrong is considered to be the place where the last event necessary to make the actor liable occurred. Thus, the locus in this case is determined by where the plaintiffs' injuries occurred.") (citations omitted); *Martin v. Julius Dierck Equip. Co.*, 374 N.E.2d 97, 101 (N.Y. 1978) (cause of action accrued in state where plaintiff was injured); *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 612 (S.D.N.Y.

[6] Novartis reserves its right to argue that the law of a different jurisdiction governs punitive damages if the Court denies summary judgment. *See, e.g., Deutsch v. Novartis Pharm. Corp.*, 723 F. Supp. 2d 521, 525-26 (E.D.N.Y. 2010) (holding that even though New York law governed plaintiffs' substantive claims, New Jersey law governed punitive damages).

2005) (applying New York law to tort claims "because that is where [plaintiff] allegedly suffered injury"). Under New York's "borrowing statute," therefore, plaintiffs' claims are subject to New York's three-year statute of limitations for personal injury actions and four-year statute of limitations for breach of warranty actions. *See* N.Y. C.P.L.R. § 214(5); N.Y. U.C.C. §2-725(1).

## III. PLAINTIFFS' CLAIMS ARE BARRED BY NEW YORK'S STATUTES OF LIMITATIONS.

### A. Plaintiffs' Tort Claims Are Barred By New York's Three-Year Statute of Limitations.

Plaintiffs' strict liability and negligence claims are subject to a three-year statute of limitations. N.Y. C.P.L.R. § 214(5); *Giordano v. Mkt. Am., Inc*., 941 N.E.2d 727, 729 (N.Y. 2010). The statutory period begins to run "from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier." N.Y. C.P.L.R. § 214-c(2).

The New York Court of Appeals has held that "the time for bringing the action begins to run under the statute when the injured party discovers the primary condition on which the claim is based." *Matter of New York Cnty. DES Litig.*, 89 N.Y.2d 506, 509 (1997) (statute of limitations begins to run when the plaintiff's injury was discovered and it is not necessary for plaintiff to have known that the injuries were caused by the drug). As the court explained:

> [T]here is nothing in either the language of the statute or its history to suggest that the Legislature intended to make the running of the Statute of Limitations depend on claimants' subjective understanding of the etiology of their conditions. Indeed, if the interpretation and rationale advanced by the dissent were to prevail, the date for commencing an action under CPLR 214-c(2) would depend on such fortuitous circumstances as the medical sophistication of the individual plaintiff and the diagnostic acuity of his or her chosen physician.

*Id*. at 514-15; *see also, e.g., Bano v. Union Carbide Corp.*, 361 F.3d 696, 709 (2d Cir. 2004) ("The fact that there may be a delay before the connection between th[e] symptoms and the

injured's exposure to a toxic substance is recognized does not delay the start of the limitations period. Nor does the worsening of a plaintiff's symptoms over time alter or postpone the accrual date.") (quotation marks and citation omitted); *Galletta*, 283 F. Supp. 2d at 916-17 ("the significant date is when plaintiff began experiencing symptoms"); *Hartman v. AT&T Corp.*, 971 F. Supp. 952, 954 (D. Md. 1996) (applying New York law) ("The injury itself marks the date of accrual, regardless of when the negligent act occurred or when the plaintiff discovered the wrong."); *Hedlund v. Cnty. of Tompkins*, 235 A.D.2d 980, 982 (N.Y. App. Div. 1997) (the date of discovery "will not be dependent upon the discovery of the cause of the injury"); *Whitney v. Quaker Chem. Corp.*, 90 N.Y.2d 845, 847 (1997) ("All that is necessary to start the limitations period is that plaintiff be aware of the primary condition for which damages are sought.").[7] A diagnosis of the cause of an injury is therefore not necessary to trigger the statute of limitations and is "completely inconsistent" with New York law. *Gaillard v. Bayer Corp.*, 986 F. Supp. 2d 241, 246 (S.D.N.Y. 2013).

For their claims to be timely, plaintiffs therefore must show that Ms. Haimowitz first experienced symptoms of her jaw injury at some point *after* December 2006. They cannot do so. To the contrary, the undisputed medical records establish the following timeline:

[7] Plaintiffs cannot argue therefore that the statute did not begin to run until Ms. Haimowitz's doctors diagnosed her with bisphosphonate-related ONJ ("BRONJ"). As noted above, the New York Court of Appeals has squarely rejected the argument that the statute of limitations does not being to run until a plaintiff receives a diagnosis or otherwise makes a connection between her symptoms and the alleged causative exposure. *Matter of New York Cnty. DES Litig.*, 89 N.Y.2d at 510-15 (holding the statute of limitations began to run when the "primary conditions that form the basis of plaintiff's complaint . . . were all known to her"); *see also Bano*, 361 F.3d at 709. The statute of limitations begins to run when the plaintiff learns of the symptoms of her injury. *See Whitney v. Quaker Chem. Corp.*, 90 N.Y.2d 845, 847 (1997); *see also Braunscheidel v. Stryker Corp.*, No. 3:12-CV-1004 (LEK/DEP), 2013 WL 1337013, at *4 (N.D.N.Y. Mar. 29, 2013) (statute of limitations begins to run when plaintiff observes "new and different pain") (McMinn Aff. Ex. 16); *Beswick v. Sun Pharm. Indus., Ltd.*, No. 10-CV-357A, 2011 WL 1585740, at *4 (W.D.N.Y. Mar. 4, 2011) (statute of limitations begins to run when patient experiences "leading edge" of symptoms) (McMinn Aff. Ex. 17).

- Ms. Haimowitz underwent extraction of a lower left molar on July 30, 1997. SUF ¶ 14.
- Ms. Haimowitz complained of swelling, pain and exposed bone at the extraction site on November 18, 1997, symptoms consistent with ONJ. SUF ¶¶ 9-11, 14.
- From November 1997 onward, Ms. Haimowitz continued to experience exposed bone and infection in her jaw despite treatment and surgery. SUF ¶¶ 14-22.
- Ms. Haimowitz reported to her oncologist Dr. Kruter in September 2002 that her oral surgeons Drs. Ruggiero (New York) and Ord (Maryland) had told her that her jaw problems were likely related to Aredia®. SUF ¶¶ 23-24.
- Ms. Haimowitz stopped taking any bisphosphonate treatment in September 2002 following that discussion with her oncologist concerning ONJ. SUF ¶ 23.
- Ms. Haimowitz's medical records from 2003 forward refer to her jaw problems as caused by Aredia®. SUF ¶¶ 26-30; *see also id.* at 25.

Ms. Haimowitz had knowledge of her jaw injury at least as early as 1997 when she had exposed bone in her jaw and certainly by September 2002, when she affirmatively told Dr. Kruter that her oral surgeons had communicated to her that bisphosphonates could have caused her jaw injury. Plaintiff had three years to file her lawsuit. Regardless of whether Ms. Haimowitz had the triggering knowledge by 1997 or by September 2002, she failed to file until December 2009 – well beyond any possible three-year period. Accordingly, her strict liability and negligence claims are time-barred and should be dismissed.

Although plaintiffs may try to avoid the statute of limitations by arguing that Ms. Haimowitz could not have discovered the cause of her jaw problems during §214-c(2)'s 3-year period and thus plaintiffs' claims are subject to the "unknown cause exception," N.Y. C.P.L.R. § 214-c(4), their claims would still be untimely, as well as procedurally barred by their failure to plead in their complaint the specific allegations required to invoke § 214-c(4). *See Gaillard*, 986 F. Supp. 2d at 249. Under § 214-c(4), a person may bring a claim a *maximum* of 6 years after discovery of an injury where she alleges: (1) "technical, scientific or medical knowledge and

information sufficient to ascertain the cause of [her] injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized," (2) that "the discovery of the cause of the injury" "occurred less than five years after discovery of the injury," and (3) she commenced her cause of action within 1 year of the causal discovery. *Annunziato v. City of New York*, 224 A.D.2d 31, 38-39 (N.Y. App. Div. 1996) ("The statute does not contemplate that a plaintiff may in effect indefinitely toll the Statute of Limitations while searching for the cause of the injury."); *see also Freier v. Westinghouse Elec. Corp.*, 303 F.3d 176, 184 (2d Cir. 2002) ("§ 214–c(4) 'gives the plaintiff five years after the discovery (actual or constructive) of the injury to ascertain its cause. If he does not (or cannot) discover the etiology within five years, then he is barred by the statute of limitations.'") (quoting N.Y.C.P.L.R. § 214–c *Practice Commentaries*, C214–c:4, at 634).

Regardless of when plaintiffs may argue Ms. Haimowitz discovered her jaw injury, the undisputed evidence indicates that Ms. Haimowitz had been told by her healthcare professionals that her jaw problems were likely caused by Aredia® by 2002 at the latest. SUF ¶¶ 23-24; *see also id.* at ¶¶ 25-30. Therefore, under any time extension §214-c(4) could have provided her, she only had until 2003 – a year from that 2002 causal discovery – to file her claims. Because Ms. Haimowitz did not file her complaint until 2009, plaintiffs' strict liability and negligence claims are untimely and should be dismissed. *Gaillard*, 986 F.Supp.2d at 250 (claim untimely where, even if cause of injury was not discovered until 2010, complaint not filed until 2012); *In re Darvocet*, No. 2:11-MD-2226-DCR, 2015 WL 2451208, at *4 (E.D. Ky. May 21, 2015) (claims untimely where alleged heart injury was discoverable by 2000 but complaint not filed until 2012) (applying New York law) (McMinn Aff. Ex. 18); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 07-MD-1871, 2015 WL 1728127, at *3 (E.D. Pa. Apr. 10, 2015) (claims

untimely where alleged injuries from medication were discovered by the end of 2006 but complaint not filed until 2013) (applying New York law) (McMinn Aff. Ex. 19).

### B. New York's Four-Year Statute of Limitations Bars Plaintiffs' Warranty Claims.

Plaintiffs' breach of warranty claims are subject to a four-year statute of limitations. N.Y. U.C.C. §2-275(1). Ms. Haimowitz's claims accrued when she received her Aredia® infusions. N.Y. U.C.C. Law § 2-725(2) ("A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made."); *Reis v. Pfizer, Inc.*, 61 A.D.2d 777, 777 (N.Y. App. Div. 1978) (breach of warranty claim accrued at the time of the sale of the alleged defective vaccine). Because Ms. Haimowitz last received Aredia® in 2002, SUF ¶¶ 2, 36, but did not file suit until 2009, plaintiffs' breach of warranty claims are barred by the statute of limitations. *See Galletta*, 283 F. Supp. at 916 (breach of warranty claims time-barred where knee implant was delivered in 1996 but lawsuit was not commenced until 2002); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 1728127, at *3 (breach of warranty claims against drug manufacturer time-barred where plaintiff last filled his prescription in 2007 but lawsuit not commenced until 2013) (McMinn Aff. Ex. 19).

## IV. MARYLAND'S STATUTES OF LIMITATIONS ALSO BAR PLAINTIFFS' CLAIMS.

### A. Plaintiffs' Tort Claims Are Barred By Maryland's Three-Year Statute of Limitations.

Even assuming plaintiffs could argue that Ms. Haimowitz's injuries arose in Maryland, which they cannot, that state also has a three-year statute of limitations for personal injury actions. *Compare* Md. Code Ann., Cts. & Jud. Proc. §§ 5-101, 5-115, *with* N.Y. C.P.L.R. §§

202, 214. Pursuant to New York's borrowing statute, New York's equivalent statute of limitations applies in this case. *See Williams*, 131 F. Supp. 2d at 455.

Plaintiffs may argue that Maryland, unlike New York, generally applies the "discovery rule" to toll the running of the statute of limitations until a person knows or reasonably should have known of the wrong. *See Bragunier Masonry Contractors, Inc. v. Catholic Univ. of Am.*, 796 A.2d 744, 757 (Md. 2002); *Am. Gen. Assurance Co. v. Pappano*, 822 A.2d 121, 1219 (Md. 2003). Application of the "discovery rule," however, does not save plaintiffs' claims. Ms. Haimowitz's medical records clearly show that she knew by 2002 that Aredia® may have caused her jaw problems, more than seven years *before* she brought this lawsuit. SUF ¶¶ 23-24; *see also id.* at ¶¶ 25-30; *Hartnett v. Schering Corp.*, 2 F.3d 90, 93 (4th Cir. 1993) (applying Maryland law) (cause of action accrued under Maryland law against drug manufacturer when plaintiff was informed by physician that she was suffering from stigmas of in-utero exposure to drug Diethyl-stilbestrol); *Phillips v. G.D. Searle & Co.*, 884 F.2d 796, 798 (4th Cir. 1989) (barring claims under statute of limitations of women who "all had some personal belief, more than three years before they filed their suits, that the [intrauterine device] had caused their injuries" with "several [having] been told by their doctors that the IUD had caused their injuries") (applying Maryland law); *Helinski v. Appleton Papers*, 952 F. Supp. 266, 272 (D. Md. 1997) (cause of action accrued under statute of limitations when physician first suggested to plaintiff that her exposure to manufacturer's carbonless copy paper could be causing her medical problems); *Morris v. Minn. Mining & Mfg. Co.*, No. BPG-13-1107, 2015 WL 1757465, at *5 (D. Md. Apr. 16, 2015) (plaintiff's claims barred where she had reason to suspect pharmaceutical product caused her alleged injury in 2007 but did not bring suit until 2013) (McMinn Aff. Ex. 20).[8] So, whether the

[8] *See also Wagner v. Allied Chem. Corp.*, 623 F. Supp. 1407, 1410 (D. Md. 1985) (plaintiffs' claims time-barred where they waited over three years before filing suit after attending party "where there was a

statute of limitations began to run in 1997 when Ms. Haimowitz first developed jaw problems, or in 2002 when she knew that Aredia® could have caused her jaw problems, plaintiffs' claims are barred.

### B. Plaintiffs' Warranty Claims Are Barred By Maryland's Four-Year Statute of Limitations.

Plaintiffs' warranty claims would also be untimely under Maryland's four-year statute of limitations. Md. Code Ann., Com. Law I § 2-275(1). Ms. Haimowitz's claims accrued when she last received Aredia® in March 2002. SUF ¶¶ 2, 36; Md. Code Ann., Com. Law § 2-725(2) ("A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made."). Because she did not file suit until December 2009, Ms. Haimowitz's breach of warranty claims are barred by the statute of limitations. *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838-39 (D. Md. 2000) (breach of warranty claims barred where plaintiff received her breast implants in May 1979 but did not bring suit until 1997 because claims expired in 1983).

## CONCLUSION

For the foregoing reasons, the Court should grant summary judgment for Novartis on all of plaintiffs' claims.

Dated: July 31, 2015

Respectfully submitted,

s/ David E. Richman
David E. Richman

s/ Donald R. McMinn
Donald R. McMinn (admitted *pro hac vice*)

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discussion of the common disabilities which past employees of [defendant employer] seemed to share" that "led the [plaintiffs] to make the crucial link between their current disabilities and their prior exposure to chemicals while working at [defendant employer]")); *Lutheran Hosp. of Maryland v. Levy*, 482 A.2d 23, 26-27 (Md. Ct. Spec. App. 1984) (evidence established that patient discovered circumstances more than three years before filing suit which ought to have put her on inquiry regarding cause of her ankle injury when she consulted physician who left her with impression that "something wrong had been done").

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**CERTIFICATE OF SERVICE**

I hereby certify that I have on this 31st day of July 2015 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's Memorandum of Law in Support of Its Motion for Summary Judgment, by electronic mail and first-class United States mail, on the following, including Plaintiffs' Liaison Counsel:

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